



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

Announced Inspection Report – Ionising Radiation (Medical Exposure) Regulations 2017

Ninewells Hospital and Medical School, Dundee
NHS Tayside

1-2 June 2021

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About our IR(ME)R inspections

Our approach

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

The quality of care approach and the quality framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality of care approach** brings a consistency to our quality assurance activity by basing all of our inspections and reviews on a set of fundamental principles and a common quality framework.
- **Our quality framework** has been aligned to the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017). These standards apply to the NHS, as well as independent services registered with Healthcare Improvement. They set out what anyone should expect when using health, social care or social work services.

We have aligned the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 to the quality framework.

How we inspect services that use ionising radiation for medical exposure

The focus of our inspections is to ensure each service is implementing IR(ME)R 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations.

What we look at

We wanted to find out:

- how the service complies with its legal obligations under IR(ME)R 2017 and addresses the radiation protection of persons undergoing medical exposures, and
- how well services are led, managed and delivered.

After our inspections, we publish a report on how well a service is complying with IR(ME)R and its performance against the Healthcare Improvement Scotland quality framework.

More information about the quality framework and quality of care approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Summary of inspection

About our inspection

We carried out an announced inspection to the Ninewells Hospital and Medical School, Dundee on Tuesday 1 and Wednesday 2 June 2021. We spoke with a number of staff including the IR(ME)R policy lead, clinical group director (radiologists), radiographers, head of radiation physics and the imaging manager. The inspection team was made up of one inspector.

Ninewells Hospital and Medical School offers plain film, computerised tomography (CT) mammography, bone density scanner called DEXA, interventional, nuclear medicine and radiotherapy. The focus of this inspection was the imaging department.

What we found

What the service did well

- NHS Tayside has effective governance arrangements for IR(ME)R in place. It also has strong leadership provided by the clinical group director, head of radiation physics and the imaging manager that supports the implementation of IR(ME)R.
- NHS Tayside employer's procedures provide good guidance for patient identification checks, which includes a variety of examples.

What the service needs to improve

- NHS Tayside must provide clarity on the recording when discussions take place explaining the risks and benefits of exposure of ionising radiation with patients who are pregnant.

Detailed findings from our inspection can be found on page 8.

What action we expect NHS Tayside to take after our inspection

This inspection resulted in three requirements and two recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements and recommendations.

An improvement action plan has been developed by the NHS board and is available on the Healthcare Improvement Scotland website.

https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx

NHS Tayside must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at the radiology department, Ninewells Hospital and Medical School for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

This section is where we report on what key outcomes the service has achieved and how well the service meets people's needs.

Domain 1 – Key organisational outcomes

High performing healthcare organisations identify and monitor key measures that help determine the quality of service delivery and the impact on those who use the service or work with the service.

IR(ME)R requires that those who refer a patient to be exposed to medical radiation, those who operate equipment and those healthcare professionals (medical and non-medical) who justify that the procedure is necessary and those who report on the image taken must be adequately trained and entitled to do so. Entitlement is given to each person involved in the process by the employer.

What we found - fulfilment of statutory duties and adherence to national guidelines

Entitlement

The process of entitlement sets out the scope of practice that an individual can carry out, such as the types of referrals, operate equipment and undertake clinical evaluations. The scope of practice depends on the individual's qualifications, role, training and experience and can change over time, following additional training or moving to a new role. The individual is required to work within this scope of practice. Employer's procedures also include what should be included in the scope of practice for each staff group.

NHS Tayside has employer's procedures in place that sets out the process for the entitlement of practitioner, operators, medical consultants and non-medical practitioners. They provide guidance on the scope of practice for each different role. Radiologists are individually entitled. Medical staff are entitled to refer within their professional group. As staff progress through their training, their scope of practice increases.

All radiologists who are Fellows of the Royal College of Radiologists are entitled to carry out justifications and clinical evaluations. A radiologist is a doctor who is specially trained to interpret diagnostic images such as x-rays and CT scans.

Their entitlement is agreed each year with their clinical lead. All radiologists work within Ninewells Hospital and Medical School and one other site within NHS Tayside.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. The imaging manager can delegate to others to act on his behalf, to entitle a healthcare professional to act as a referrer for a range of medical exposures. Non-medical referrers also have their entitlement agreed each year.

We are assured that NHS Tayside has clear processes and procedures in place to demonstrate that the approval of non-medical referrers' entitlement is appropriately managed.

Referral

A referral can only be made by a person who is entitled to do so (within their scope of practice). Referrals are received by the radiology department from a variety of sources from within the hospital, other NHS Tayside services, such as from the community. Referrals are received electronically.

When a referral is made through the electronic system, it will include the referrer's role, such as a doctor in training, consultant or non-medical referrer. Radiographers are familiar with the scope of practice for medical staff and non-medical referrers. When a referral is made, the person reviewing the referral can check the referrer's scope of practice if required. A full list is easily available on the intranet and includes their scope of practice. Referrals made that are outwith the referrer's scope of practice, are rejected.

Justification

Radiologists and radiographers will review referrals received and consider if the information is sufficient to justify the exposure. They also check for any previous exposures for potential duplication. A small number of specialist groups, such as orthopaedic surgeons are entitled to justify specific exposures as part of their specialty.

Radiologists review all referrals, other than plain film, to ensure that information is sufficient to justify the referral. Radiographers review all referrals for plain film exposure. All record their justification in the radiology information system, except the specialist groups.

Radiologists told us they would detail the correct protocol for the medical exposure of ionising radiation is selected, when required.

Staff told us if a referral was received with insufficient information that was not an emergency, the radiologist would reject the request. If an exposure was required urgently they would telephone the referrer to request further information. They would then record any additional information and justify the exposure.

Records

During our inspection, we saw information recorded on the radiography information system, including:

- the correct patient information
- identification checks
- scanned documents, such as pregnancy check questionnaires
- details of the referrer and operator
- radiation dose
- justification, and
- clinical evaluation.

Radiography staff could describe the checks they would carry out prior to recording this information. For example, they review clinical history against the patient information. They also demonstrated how they recorded the dose information. Radiographers act as the final check to ensure that the right patient gets the right exposure. They are positively encouraged to be vigilant.

What needs to improve

NHS Tayside must identify individuals to act as a referrer, practitioner or operator. We saw these procedures are in place for non-medical referrers who received an individual entitlement letter that set out their scope of practice. Some medical staff are individually entitled, such as cardiologists and orthopaedic surgeons, however not all medical staff are individually entitled as referrers (requirement 1).

While non-medical referrers' entitlement is reviewed once each year, we saw no mechanism in place to record whether their scope of practice had changed since the last review. There was also no requirement for the non-medical referrer to proactively inform the radiology department about a change to their practice. No examples of this were noted, however it could result in non-medical referrers being inappropriately entitled (recommendation a).

Requirement 1

- NHS Tayside must ensure that each medical member of staff is provided with their individual scope of practice.

Recommendation a

- NHS Tayside should develop a system to ensure any changes in a non-medical referrers' role that impacts their scope of practice is recorded.

Service delivery

This section is where we report on how well the service is delivered and managed.

Domain 5 – Safe, effective and person-centred care delivery

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

Each organisation must appoint an IR(ME)R lead who will take responsibility for the implementation of the systems and processes to ensure statutory requirements are being met. Clear governance and processes must be in place to demonstrate that IR(ME)R is managed and implemented.

What we found - safe delivery of care

Safety culture

The IR(ME)R policy lead described a culture that promotes reporting and learning from incidents and near misses to drive improvements. Everyone we spoke with during the inspection was positive about the safety culture within NHS Tayside.

The diagnostic operational leadership team were clear that radiation safety was a priority and they wanted to reduce the exposures where possible.

Radiographers and radiologists feel supported to take the time needed to undertake their duties and to challenge referrals when required.

Employer’s procedures

All NHS boards have a duty under IR(ME)R to develop written procedures in line with schedule 2 of IR(ME)R 2017. These procedures are referred to as employer’s procedures. These are intended to provide a framework under which professionals can practice. NHS Tayside has developed five levels of employer’s procedures:

- level 1 applies to the whole NHS board, including all modalities
- level 2 are standard operating procedures that are modality specific across various sites

- level 3 are called department protocols, which are usually site specific within a hospital, and
- level 4 and 5 procedures provide specific guidance for operators, which supports level 3 procedures.

The use of level 1 procedures is limited. Employer's procedures for each modality start in level 2 procedures. While NHS Tayside is unique in having five levels of employer's procedure, staff we spoke with understood where to access the relevant information.

The level 1 employer's procedure (Quality assurance of employer's written procedures and protocols) details that level 1 procedures must be authorised by the IR(ME)R policy lead. Levels 2-5 procedures are authorised by clinical leads and senior managers, who are authorised to do so.

Employer's procedures are required to be reviewed every year. Level 1 procedures are reviewed by the author. The imaging manager delegates level 2-5 procedures to be reviewed to a nominated person in the diagnostic department. The review of the employer's procedures is discussed at the radiation safety committee.

Radiographers told us they are informed of any updates. Changes to employer's procedures are communicated through the NHS board's intranet and document management system and team huddles.

The implementation of the employer's procedures is monitored through clinical audits. We were also told assurance is provided by monitoring the low number of incidents recorded.

The document management system monitors when staff have accessed a document. This allows staff to demonstrate have looked at revised and new procedures.

All employer's procedures we reviewed were clear and provided detailed guidance for staff on how to comply with IR(ME)R.

Patient identification

NHS Tayside's level 2 procedures provide guidance on patient identification checks. Including, questions to be asked by the receptionist to the department, what to do when identifying babies, how to identify patients in intensive care and patients that are unable to identify themselves.

All the radiographers we spoke with could clearly describe how to carry out identity checks and are familiar with the employer's procedures. They told us they would ask the patient their name, date of birth and address prior to any exposures. They would not proceed with an exposure if patient identification checks are not completed.

Staff also have access to interpreter services should they require it.

Risk benefit conversations

Patients are provided with information on the risks and benefits prior to their exposure.

Radiographers told us they would also explain the risks of radiation exposure to patients who ask for further information at the time of their appointment. NHS Tayside's level 2 procedure (Provision of information relating to benefits and risks of an exposure) sets out the comparison between exposures from different type of equipment and the equivalent natural background radiation, which support informed discussion with patients.

We saw information posters displayed in the diagnostic department and in changing facilities to inform patients of the low risk of an exposure. The posters also highlighted the need to inform a member of staff of any possibility that the patient may be pregnant.

Making enquiries of individuals who could be pregnant

We were told that anyone of child bearing capacity aged between 12 and 55, for exposures between the lower diaphragm and upper thigh are directly in the primary beam, would be asked the pregnancy status questions.

NHS Tayside has an operation procedure in place for checking when a patient is pregnant. The procedure includes a flow diagram that provides guidance on when the exposure can go ahead. It states the clinician or radiologist must be involved in discussions when a patient is pregnant and an exposure is still required. If the decision has made to go ahead with the exposure, this will be discussed with the patient. A record of the discussion with the patient, and the decision to proceed, should be recorded in the radiology information system against the patient record. Radiologists told us that they would encourage the clinician to discuss the risk benefits with the person who is pregnant.

Any time a pregnant individual is exposed, a form is sent to the medical physics experts, who records the foetal exposure as an additional control measure.

Carers and comforters procedures

NHS Tayside has clear guidance on the authorisation of an exposure to a carer or comforter, such as the mother of a child. If an exposure is authorised, it will be recorded. All radiographers we spoke with were clear they would try to avoid exposure of a carer or comforter where possible.

General duties in relation to equipment

Staff carry out routine quality assurance checks and could describe the procedure if results from these checks are outside the expected parameters. Staff told us they would report any concerns to the superintendent or go direct to the medical physics experts for advice. All staff could describe the procedure when a service engineer is onsite and what documentation is to be completed. We saw documentation from the service engineer and quality assurance records in place.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable.

Medical physics experts use dose audit information to set local dose reference levels. Where local dose reference levels are not available, NHS Tayside can use UK or European dose reference levels

All operators we spoke with could describe how they would select the correct protocol for the intended purpose. Many exposures have a dose reference level that provides an indicator of the level of expected exposure.

The equipment used to expose patients to ionising radiation has a variety of pre-set protocols that help deliver standardised exposures. These can be modified for adults and children to take account of different body sizes. All operators we spoke with could describe how they would select the correct protocol for the intended purpose and were aware of the dose reference levels. Should the recorded value of an exposure be outside agreed limits without reason, an investigation will be carried out. The investigation would consider the patient details, the quality of the image taken, the protocol used and scan range.

Radiologists we spoke with described the balance between image quality and the dose to obtain clinically effect images. They also told us they would always consider an alternative to ionising radiation where practicable.

NHS Tayside does not have an imaging optimisation team. However, an NHS Tayside Imaging Radiation Protection group considers image optimisation. Radiologists also discuss optimisation at their clinical forum every week.

What needs to improve

We are not assured that risk benefit discussions with patients who are pregnant are recorded on the radiology information system, in line with the NHS board's employer's procedures. We were told that it might only be recorded in the patient notes, which is not always obvious to the radiographer prior to carrying out the exposure. This means the radiographer has to confirm that discussions have taken place with the referrer, then record it on the radiology information system (requirement 2).

Requirement 2

- NHS Tayside must provide clarity on the recording of the discussions of the risks and benefits of exposure of ionising radiation with patients who are pregnant. It must provide details of who should be involved have the discussion and when these discussions should take place and where the evidence of the discussion should be recorded.
- No recommendations.

Domain 6 – Policies, planning and governance

High performing healthcare organisations translate strategy into operational delivery through development and reliable implementation of plans and policies, and have effective accountability, governance and performance management systems in place.

What we found - risk management, audit and governance

NHS Tayside's governance arrangements for IR(ME)R are effective and ensured enhanced understanding and increased communication for radiography, radiology and medical physics expert staff. Strong leadership was evident from the operational leadership team who proactively ensured implementation of IR(ME)R.

NHS Tayside's IR(ME)R policy provides a clear overview of how IR(ME)R is implemented. It provides details of the roles and responsibilities of the different staff groups, such as the chief executive, associate medical director, referrers, practitioners, operators and medical physics experts. It also provides guidance on the different levels and types of employer's procedures available.

The associate medical director of the access and assurance directorate is the IR(ME)R policy lead for NHS Tayside. They are relatively new in post and confirmed a handover was provided before taking on the role.

The radiation safety committee meets twice a year and is chaired by the IR(ME)R policy lead. The committee is provided with assurance about the implementation of IR(ME)R by input from committee members, risk register and reports submitted by each modality.

A report is produced by the head of radiation physics (who is a member of the radiation safety committee) every 6 months. This report is submitted to the NHS board's care governance committee, that includes representation by the chief executive is a member of. The report provides details on the implementation of IR(ME)R and highlights any areas of concern required to be escalated. This is the only link to the chief executive.

The clinical group director (a radiologist), image manager and head of radiation physics provide operational leadership within the diagnostic department. All three are proactively involved in a wide variety of IR(ME)R related activities including dose optimisation, clinical audit, employer's procedures and non-medical referrers.

IR(ME)R is also discussed at the Ninewells Hospital and Medical School radiation protection meeting, chaired by the radiology imaging manager. This group meets every month and is attended by radiography leads and radiologist leads for different types of imaging. The group discusses quality assurance, incidents and equipment replacement. We were told that this group has been running for 1 year.

Radiologists meet every week to discuss IR(ME)R related issues, such as the Royal College of Radiologists IR(ME)R guidance. They also consider whether any incidents are considered significant and should be escalated to the senior executive team and chief executive.

Contracted services

NHS Tayside only use a private company to provide radiologists that undertake clinical evaluation of images for outpatient clinics.

Before contracting the private company, the NHS board's clinical group director carried out a review of radiologists employed by company. NHS Tayside told us it carries out regular quality assurance of 20% of all patients diagnosed with cancer. Any discrepancies are discussed with the company. The private company also undertakes its own quality assurance through audits and undertakes a double review of 5% of their images. The results are shared with NHS Tayside.

Clinical audit

During our inspection, we reviewed the results of the audits carried out. NHS Tayside has a programme of audits in place in the radiology department, as set out in their level 2 employer's procedure (Clinical audit). Managers carry out an audit of 20 patient examinations every month. Feedback is given to any staff where the areas of learning are identified. Each radiology department also undertakes site specific audits. Audit results are collated and reported to the radiation safety committee. Radiologists who are training undertake audits as part of their role. While these may not be specific to aspect of IR(ME)R, they can include aspect of IR(ME)R compliance.

What needs to improve

Images taken by specialist, such as orthopaedic surgeons, record justifications in the patient's notes. No audits are currently carried out of these patients' notes to ensure they are being completed appropriately in line with IR(ME)R (recommendation b).

- No requirements.

Recommendation b

- NHS Tayside should extend the current audit programme to include records that are outside the radiology information system.

Domain 7 – Workforce management and support

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

What we found - staff recruitment, training and development

Expert advice

NHS Tayside employs three medical physics experts and three support staff for diagnostics department. They provide advice on compliance with IR(ME)R. They are involved in a variety of other areas including:

- commissioning of new equipment
- acceptance testing of new equipment
- quality assurance of equipment
- dose monitoring

- training
- analysis of incidents
- incident investigations, and
- development of dose reference levels.

They also provide advice on whether an incident requires to be reported to Healthcare Improvement Scotland.

We were told medical physics experts are regularly available in the department, easy to contact and:

- ‘It’s a bonus to have the medical physics expert staff on site.’

The current medical physics expert resource has been reviewed based on the European Federation of Organisations for Medical Physics. Policy Statement No. 7.1 and found to be comparable. Performance indicators are used to monitor the capacity of the medical physics experts on a variety of areas including optimisation, quality control and patient dose audits. We were told there were no concerns.

Training

We found comprehensive training records in place for staff involved in medical exposure to radiation.

Once a radiographer qualifies, NHS Tayside provides induction and ongoing training. We saw clear training records for operators of equipment in the department, including CT and plain film equipment. A radiographer’s training record is closely linked to their entitlement. We reviewed a sample of records, which were all up to date.

Operators must be trained on each specific piece of equipment. All radiographers we spoke with were clear they had been received appropriate training.

Radiologists’ training and continual professional development is managed through their annual appraisals and medical revalidation process, which takes place every 5 years.

Trainee radiologists follow a programme of training. As they progress through the training and demonstrate their competencies, their scope of practice increases to allow them to report more complex imaging.

What needs to improve

While we saw evidence of continual education for radiologists and radiographers, it was not always possible to identify training that related specifically to IR(ME)R. It was also unclear what continual education was needed for staff outside radiology, who have obligations under IR(ME)R (requirement 3).

Requirement 3

- NHS Tayside must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R.

- No recommendations.

Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of a service to comply with the Regulations. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.
- **Recommendation:** A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

Domain 1 – key organisational outcomes	
Requirement	
1	NHS Tayside must ensure that each medical member of staff is provided with their individual scope of practice (see page 11). <i>Regulation 6(1)a, Schedule 1(b) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
a	NHS Tayside should develop a system to ensure any changes in a non-medical referrers' role that impacts their scope of practice is recorded (see page 11).

Domain 5 – Safe, effective and person-centred care delivery	
Requirement	
2	NHS Tayside must provide clarity on the recording of the discussions of the risks and benefits of exposure of ionising radiation with patients who are pregnant. It must provide details of who should be involved have the discussion and when these discussions should take place and where the evidence of the discussion should be recorded (see page 16). <i>Regulation 6(1)a, Schedule 1(i) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
None	

Domain 6 – Policies, planning and governance	
Requirements	
None	
Recommendation	
b	NHS Tayside should extend the current audit programme to include records that are outside the radiology information system (see page 18).

Domain 7 – Workforce management and support	
Requirement	
3	NHS Tayside must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R (see page 20). <i>Regulation 6(3)(b)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
None	

Complaints/Concerns

If you would like to raise a concern or complaint regarding any aspect of the inspection then please discuss this with the lead inspector in the first instance.

If there is a concern or complaint about the conduct of an inspector please contact Kevin Freeman-Ferguson, head of service review, kevin.freeman-ferguson@nhs.scot in the first instance to discuss your concerns in more detail.

Alternatively, Healthcare Improvement Scotland has a complaint and feedback service that can be contacted directly. Details can be found on our webpage.

http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx

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